

GENZYME CANADA INC. 2700 Matheson Blvd. West Sulte 800, West Tower Mississauga. Ontorio L4W 4V9 Phone: 905.625.0011 Toll Free: 877.220.8918 Fax: 905.625.7811

Website: www.genzyme.ca

Via Fax: 1-613-952-7626

March 3, 2008

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Dear Ms. Dupont:

I am writing to provide feedback on the PMPRB's discussion paper, "Options for Possible Changes to the *Patented Medicines Regulations*, 1994 and the Excessive Price Guidelines," which was released on January 31, 2008.

Genzyme Canada Inc. is a member of the biotechnology community in Canada and is dedicated to making a positive impact on the lives of people with serious diseases. Internationally, Genzyme Corporation is a leader in the effort to develop and apply the most advanced technologies in the life sciences. We are committed to innovation in the biotechnology sector to address unmet medical needs. Our products and services are focused on rare inherited disorders, kidney disease, cancer, and other fields. We have a very real interest in the policies of the PMPRB as they impact the biopharmaceutical market in general and the specific and unique sectors in which Genzyme Canada operates.

We are a member of BIOTECanada and fully endorse the submission made by BIOTECanada with respect to the discussion paper. As a leader in the development and supply of products for rare disorders, we particularly draw your attention to the comments in the BIOTECanada submission about the concerns with respect to the proposals on re-setting the MNE price in the case of a drug indicated for a rare, life threatening disease. We also share the concerns about the other aspects of the proposals to re-set the MNE price and the proposals with respect to "any market price review" and we urge the PMPRB not to proceed with these proposals.

We also endorse the submissions by BIOTECanada with respect to the options to address the LEO Pharma - Dovobet matter. Genzyme Canada is very concerned about the

potential for the options to impact the supply of medicines for compassionate purposes. The existing PMPRB policies, as set out in the April 2000 NEWSletter and the guidelines, have permitted companies like ours to develop programs that are most appropriate in addressing the needs of patients.

In some cases, the supply of free product for certain patients could form part of broader funding agreements with governments which extend over fixed time periods and which may be renewable. The options being considered by the PMPRB should avoid creating any disincentives to manufacturers to take part in such agreements.

The option of continuing the April 2000 policy, through a regulatory change if necessary, is in our view the most straight forward way of addressing the *LEO Pharma - Dovobet* matter. If the Board were to move in other directions, we would encourage that there first be full analysis of the implications for compassionate programs in particular and appropriate measures for transition and the protection of agreements currently in place.

Yours very truly,

Brian Lewis, General Manager

Genzyme Canada Inc.